OCT 1 5 2009

510(k) Summary

510(k) Number: K091624

Date Prepared May 29, 2009

Submitter Information

Submitter's Name/Address:
Via Biomedical, Inc.
6655 Wedgwood Road
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Maple Grove, MN 55311

Contact Person:
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President & CEO
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Device Information

Trade Name:	Stent Graft Balloon Catheter
Common Name:	Catheter, Percutaneous
Classification Name:	Catheter, Percutaneous
Product Code:	DQY
Regulation:	Class II, 21 CFR 870.1250
Panel:	Cardiovascular

Performance Standards

No performance standards applicable to this product have been developed under Section 514 of the Act.

Predicate Devices

Predicate Device	Manufacturer	510(k) Status
Reliant Stent Graft Balloon Catheter	Medtronic, Inc.	K050038
Coda Balloon Catheter	Cook, Inc.	K032869
Equalizer Balloon Catheter	Boston Scientific, Inc.	K021721

Device Description

The Stent Graft Balloon Catheter is a multi-lumen catheter which has a compliant polyurethane balloon with a maximum diameter of 50mm. The device is available in two usable lengths, 65 cm and 100 cm. The device is designed to accommodate a 0.038" diameter or smaller guidewire. Two radiopaque marker bands are placed within the balloon to facilitate balloon placement prior to inflation. The device is a single use, sterile device.

Intended Use/Indications for Use

The Stent Graft Balloon Catheter is intended for temporary occlusion of large vessels, or to expand vascular prostheses.

Summary of Non-Clinical Testing

The Stent Graft Balloon Catheter underwent mechanical, performance, and biocompatibility testing to verify that the device functions in a safe and effective manner. The results of the tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use.

Statement of Equivalence

The Stent Graft Balloon Catheter is substantially equivalent to the predicate devices listed above based on a comparison of the indications for use and the technological characteristics. The testing performed confirms that the Stent Graft Balloon Catheter will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 1 5 2009

Via Biomedical, Inc.
C/O Fernando Di Caprio, President and CEO
6655 Wedgwood Road, Suite 150
Maple Grove, MN 55311

Re: K091624
Trade Name: Stent Graft Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II
Product Code: DQY, MJN
Dated: September 24, 2009
Received: September 25, 2009

Dear Mr. Di Caprio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K091624

Device Name: Stent Graft Balloon Catheter

Indications for Use:

The Stent Graft Balloon Catheter is intended for temporary occlusion of large vessels, or to expand vascular prostheses.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Jackson

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091624